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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,439	12/07/2000	Paul C. Anderson	950.030US2	1720

7590 11/19/2002  
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/19/2002

60

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/732,439

Applicant(s)

ANDERSON ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 59-96 is/are pending in the application.
- 4a) Of the above claim(s) 64-71 and 74-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-63, 72 and 73 is/are rejected.
- 7) ☒ Claim(s) 72 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on April 19, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 59-63 and 72-73, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the restricted claims recite a common osmoprotectant and water use strategy and therefore would require a common search. The traversal is also on the ground(s) that amendment of the claims to refer to the elected claim 59 now links the claims.

This is not found persuasive because although the searches of the three groups may overlap, they are not coextensive. A search of Group I requires a search of plants that are not claimed in Groups II or III, and a search of Group II requires a search of methods that are not claimed in Groups I or III. Accordingly, claims 64-71 and 74-96 are withdrawn from consideration as being directed to nonelected inventions, and claims 59-63 and 72-73 are examined on the merits in the instant application.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claim 72 is objected to because it depends upon nonelected claim 68. Appropriate correction is required.

***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed August 6, 2001, Paper No. 7, is attached to the instant Office action.

Applicant's IDSs filed December 7, 2000 and June 1, 2001 were unavailable for consideration by the Examiner at the time of the instant Office action.

***Specification***

The specification is objected to because the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The specification is objected to because the text on page 8 line 25 is blurred.

The specification is objected to because the description of the drawings does not include a description for each figure of the drawings.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-63 and 72-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transformed monocot plant and a fertile transgenic *Zea mays* plant comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline.

The claims do not recite the specific identity of any particular recombinant DNA with which the plants have been transformed. Absent reference to the particular identity of the recombinant DNA a critical element of the claimed invention remains undefined, such that the invention is not adequately described. Furthermore, the specification does not describe any plant comprising any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline. The specification also does not describe any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline. Given that proline is an amino acid found in virtually all organisms, a variety of structurally and functionally distinct proline biosynthetic enzymes exist that are encoded by genes from divergent plant, animal and microbial species.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the

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species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 59-63 and 72-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a transformed monocot plant which is substantially tolerant or resistant to a reduction in water availability, the cells of said plant comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, wherein said enzyme is expressed in an amount effective to confer tolerance or resistance to a reduction in water availability. The claims are also drawn to a fertile transgenic *Zea mays* plant comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline.

The specification does not disclose the identification or isolation of any gene encoding any enzyme involved in proline synthesis, or any plant comprising any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline. The specification does not provide any guidance for one skilled in the art to determine which recombinant DNA to use and how to express it, because the specification does not disclose any plant tolerant or resistant to a reduction in water availability that comprises any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline.

The ability of a recombinant DNA encoding an enzyme involved in proline biosynthesis to confer tolerance or resistance to a reduction in water availability is unpredictable. The ability of a proline biosynthetic enzyme to confer tolerance or resistance to a reduction in water availability would be limited by the cellular environment in which the enzyme is expressed. Enzymatic function would be affected by the amount of enzyme expressed, the availability of substrate, and the presence or absence of other factors that might affect enzyme activity or the accumulation of proline. For example, Hu et al. (Proc. Natl. Acad. Sci. USA Vol. 89, pages 9354-9358, October 1992) teach that the plant proline biosynthetic enzyme  $\Delta^1$ -pyrroline-5-carboxylate synthetase is subject to feedback inhibition by proline (page 9357 Figure 3). Such feedback inhibition could limit the ability of a  $\Delta^1$ -pyrroline-5-carboxylate synthetase transgene to confer tolerance or resistance to a reduction in water availability.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify a multitude of non-exemplified proline biosynthesis enzymes or the genes encoding them from a multitude of

sources, to isolated said genes, and to evaluate the ability of a multitude of non-exemplified genes to confer drought tolerance to plants transformed therewith.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 61 is indefinite in the recitation of "increased", as increased is a relative term lacking a comparative basis.

Claim 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 73 is indefinite in the recitation of "transgenic seed". While the claim recites that the transgenic seed is "of the transformed plant of claim 72", it is unclear what transgene the seed is transgenic for, as transgenic seed of the transformed plant of claim 72 could contain transgenes in addition to those used in the method of claim 68.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in-
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b)



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only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 59-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Verma et al.

(U.S. Patent No. 5,639,950, issued June 17, 1997, filed June 29, 1994, having an effective filing date of September 29, 1992).

The claims are drawn to a transformed monocot plant which is substantially tolerant or resistant to a reduction in water availability, the cells of said plant comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, wherein said enzyme is expressed in an amount effective to confer tolerance or resistance to a reduction in water availability, and wherein the transformed plant has an improved osmotic potential when the total water potential of the transformed plant approaches zero.

Verma et al. teach corn, wheat, barley and rye monocot plants comprising a recombinant DNA encoding  $\Delta^1$ -pyrroline-5-carboxylate synthetase which catalyzes the synthesis of the osmoprotectant proline (column 17 claim 5 and column 18 claim 14). Although Verma et al. do not explicitly teach the amount of  $\Delta^1$ -pyrroline-5-carboxylate synthetase expression in said plants, the  $\Delta^1$ -pyrroline-5-carboxylate synthetase expression would necessarily be expressed in an amount effective to confer tolerance or resistance to a reduction in water availability, as the monocot plants taught by Verma et al. are drought resistant. Although Verma et al. do not explicitly teach that the plants have an improved osmotic potential when the total water potential of the transformed plant approaches zero, the plants would necessarily have an improved osmotic potential when the total water potential of the transformed plant approaches zero, as the monocot

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plants taught by Verma et al. are drought resistant and are transformed with an enzyme which catalyzes the synthesis of the osmoprotectant proline.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59-63 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Verma et al. (U.S. Patent No. 5,639,950) in view of Rayapati et al. (Plant Physiology, 1989, Vol. 91, pages 581-586) and in light of Applicant's admitted prior art.

The claims are drawn to a fertile transgenic *Zea mays* plant comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, including a recombinant DNA that further comprises a segment encoding an amino terminal chloroplast transit peptide, and a monocot plant regenerated from cells transformed with an expression cassette comprising a recombinant DNA encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline and encoding an amino terminal chloroplast transit peptide.

The teachings of Verma et al. are discussed *supra*.

Verma et al do not teach a DNA segment encoding an amino terminal chloroplast transit peptide.

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Rayapati et al. teach that the proline biosynthetic enzyme  $\Delta^1$ -pyrroline-5-carboxylate reductase ( $\Delta^1$ -pyrroline-5-carboxylate synthetase) is localized in chloroplasts (page 582 column 2 last paragraph through page 583 column 2 second full paragraph).

Applicant teaches that DNA segments encoding amino terminal chloroplast transit peptides were known and used in the plant transformation art at the time of Applicant's invention (page 39 lines 7-9).

Given the success of Verma et al. in transforming plants with a recombinant DNA encoding  $\Delta^1$ -pyrroline-5-carboxylate synthetase which catalyzes the synthesis of the osmoprotectant proline, given the teaching of Rayapati et al. that native  $\Delta^1$ -pyrroline-5-carboxylate synthetase is localized in chloroplasts, and given that that DNA segments encoding amino terminal chloroplast transit peptides were known and used in the plant transformation art at the time of Applicant's invention, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to transform a plant with a recombinant DNA encoding both a proline biosynthetic enzyme and a chloroplast transit peptide, give the express purpose of making a transgenic plant transformed with a recombinant DNA encoding both a proline biosynthetic enzyme and a chloroplast transit peptide, without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made. Seed propagation of desirable genotypes is well known.

**Remarks**

No claim is allowed.

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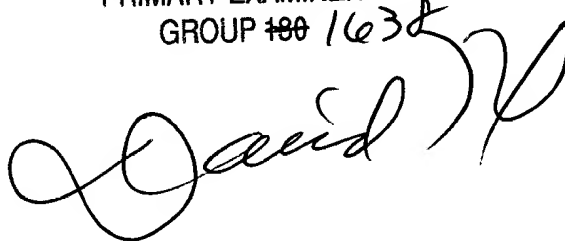
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
November 15, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~100~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the typed name and group number.